

REMARKS

By way of summary, Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 were previously pending in the above-identified application. Claims 25, 27, 47, 49, 60, 62, 72, 74, 87 and 88 have been amended. Claims 28, 50, 63, 75, 83-86 and 89 remain as previously presented. Accordingly, Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 are presented for further consideration.

A. Response to Rejections of Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 under 35 U.S.C. § 103

The Office Action rejected Claims 25, 27, 28, 47, 49, 50, 60, 62, 63, 72, 74, 75 and 83-89 under 35 U.S.C. § 103(a). Claims 25, 27, 28, 60, 62, 63 and 83-89 were rejected as obvious over U.S. Pub. No. 2001/0012950 by Nishtala et al. ("Nishtala") in view of U.S. Pat. No. 4,738,666 to Fuqua ("Fuqua") and U.S. Pat. No. 6,030,364 to Durgin et al. ("Durgin"). Claims 47, 49, 50, 72, 74 and 75 were rejected as being unpatentable over Nishtala in view of Fuqua, Durgin and U.S. Pat. No. 5,810,776 to Bacich et al. ("Bacich"). Applicants respectfully disagree and traverse these rejections, the characterization of the pending claims, and each and every implicit and explicit official notice.

1. Independent Claim 25

Claim 25 recites, and Nishtala, either alone or in combination with Fuqua and Durgin, fails to disclose, *inter alia*, "a circumferentially continuous elongate tubular structure," "a tapered region between the distal region and the proximal region," "the longitudinal creases of the distal region comprising two creased outer sections that lie on a perimeter of the distal region and face each other and two creased inner sections that lie within the perimeter of the distal region and face away from each other, all of the longitudinal creases generally positioned on one side of the distal region," and "inflating a balloon that is positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand and unfold said distal region of said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to said second, greater cross-sectional profile."

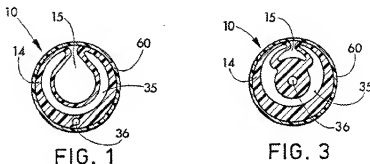
The Office Action acknowledged that Nishtala fails to disclose "a tapered region between the distal region and the proximal region," but relied on Durgin to disclose this feature. However, Nishtala is directed to a "single integrated device that can reach any of a plurality of

expanded diameters upon actuation by a user of an actuating mechanism which directs and controls the dilation of a dilating element.” Nishtala Abstract. Durgin discloses a “minor diameter section of the sheath...comprised of split fingers.” Durgin Spec., col. 7, lines 62-65. “The sheath fingers...are formed by removing two longitudinal slices from the sheath body” and are then “folded or overlapped.” Durgin Spec., col. 7, line 66 – col. 8, line 1; col. 8, lines 19-20. However, these fingers could not, without undue experimentation, be overlapped and/or combined with an actuating mechanism in such a way as to “reach any of a plurality of expanded diameters.” For example, it is unclear how an actuating mechanism could be operably connected to the fingers in such a way as to be able to expand the fingers to a plurality of diameters. Accordingly, the proposed combination of Nishtala and Durgin would “render Nishtala “unsatisfactory for its intended purpose.” M.P.E.P. § 2143.01(V). Additionally, the combination of Nishtala and Durgin would not result in a “circumferentially continuous elongate tubular structure,” but would instead consist of “longitudinal slices,” as disclosed in Durgin.

The Office Action further acknowledged that Nishtala fails to disclose “the distal region having a first, folded, smaller cross-sectional profile,” and relied on Fuqua to disclose this feature. However, Fuqua is directed to a catheter which “expand[s] to full size as a result of the memory of the system.” Fuqua Spec., col. 5, lines 26-27. Therefore, a person having ordinary skill in the art at the time of invention would not have been motivated to combine the catheter of Fuqua with a balloon such that “inflating a balloon that is positioned within an interior lumen of said distal region of said elongate tubular structure [] expand[s] and unfold[s] said distal region of said elongate tubular structure radially around its longitudinal axis from said first, smaller cross-sectional profile to said second, greater cross-sectional profile.”

In addition, it would not be obvious to position a balloon within the interior lumen of the plastic tube 14 of Fuqua (see illustrations from Fuqua below). As noted above, Applicants believe that it would not be obvious to add a balloon to the device of Fuqua. However, even assuming, *arguendo*, that a balloon was added to the device of Fuqua it would not be obvious to place the balloon within the interior lumen of the tube 14. Expansion in Fuqua is accomplished by removing a sheath from the catheter, thereby allowing the catheter to expand as a result of its memory. Fuqua Spec., col. 5, lines 23-27. Thus, even assuming, *arguendo*, that a motivation does exist to combine Fuqua with a balloon, the motivation would be to “cause[] the sheath [60]

to separate at the perforations.” Fuqua Spec., col. 5, lines 41-41. Accordingly, one of skill in the art would place the balloon within the fold 15 and not within the interior lumen of the tube 14.



Moreover, Nishtala, Fuqua and Durgin do not disclose “the longitudinal creases of the distal region comprising two creased outer sections that lie on a perimeter of the distal region and face each other and two creased inner sections that lie within the perimeter of the distal region and face away from each other, all of the longitudinal creases generally positioned on one side of the distal region.”

For at least the reasons expressed above, Applicants respectfully request that the rejection of Claim 25 be withdrawn and that this claim be passed to allowance.

2. Independent Claim 47

Claim 47 recites and, for at least similar reasons as expressed above in relation to Claim 25, Nishtala, either alone or in combination with Fuqua, Durgin, and Bacich, fails to disclose, *inter alia*, “a circumferentially continuous elongate tubular structure,” “the distal region having...longitudinal creases...the longitudinal creases comprising two creased outer sections that lie on a perimeter of the distal region and face each other and two creased inner sections that lie within the perimeter of the distal region and face away from each other...all of the longitudinal creases positioned generally opposite the side of the distal region on which the leading edge is positioned such that no longitudinal creases are positioned on the same side of the distal region on which the leading edge is positioned,” and “inflating a balloon that is positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand and unfold said distal region of said elongate tubular structure from said first, smaller cross-sectional profile to said second, greater cross-sectional profile.”

Furthermore, Nishtala, either alone or in combination with Fuqua, Durgin, and Bacich, fails to disclose “the distal region having...a beveled distal tip...the beveled distal tip comprising a leading edge and a trailing edge, all of the longitudinal creases positioned generally opposite the side of the distal region on which the leading edge is positioned such that no longitudinal creases are positioned on the same side of the distal region on which the leading edge is positioned.” While the Office Action expressly interprets the guide channel 120 of Bacich as the “elongate tubular body” of Claim 47, it is unclear whether the Office Action is interpreting element 108 or element 126 of Bacich (shown together in Bacich Fig. 2) as disclosing the beveled distal tip of Claim 1.

If the Office Action interprets element 108 as the beveled distal tip, Bacich does not disclose guide channel 120 as having element 108. Rather, as demonstrated in Bacich Figs. 3-4 and 11, the guide channel 120 is constructed of a membrane 140 proximal to and distinct from element 108 and which itself does not have a beveled distal tip.

On the other hand, if the Office Action interprets element 126 as the beveled distal tip, Applicants point out that element 126 represents the beveled distal tip of dilator 114, not the guide channel 120. As shown in Fig. 2, the guide channel 120 may take the shape of the dilator 114; however, the guide channel itself is not disclosed as having a “beveled distal tip comprising a leading edge, a trailing edge, and an aperture.”

For at least the reasons expressed above, Applicants respectfully request that the rejection of Claim 47 be withdrawn and that this claim be passed to allowance.

3. Independent Claim 60

Claim 60 recites and, for at least similar reasons as expressed above in relation to Claim 25, Nishtala, either alone or in combination with Fuqua and Durgin, fails to disclose, *inter alia*, “a circumferentially continuous elongate tubular structure,” “a tapered region between the distal region and the proximal region,” “the longitudinal creases of the distal region comprising two creased outer sections that lie on a perimeter of the distal region and face each other and two creased inner sections that lie within the perimeter of the distal region and face away from each other, all of the longitudinal creases generally positioned on one side of the distal region,” and “inflating a balloon that is positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand and unfold said distal region of said elongate tubular

structure from said first, smaller cross-sectional profile to said second, greater cross-sectional profile.” Accordingly, Applicants respectfully request that the rejection of Claim 60 be withdrawn and that this claim be passed to allowance.

4. Independent Claim 72

Claim 72 recites and, for at least similar reasons as expressed above in relation to Claims 25 and 47, Nishtala, either alone or in combination with Fuqua, Durgin, and Bacich, fails to disclose, *inter alia*, “a circumferentially continuous elongate tubular structure,” “the distal region having...longitudinal creases, and a beveled distal tip...the longitudinal creases comprising two creased outer sections that lie on a perimeter of the distal region and face each other and two creased inner sections that lie within the perimeter of the distal region and face away from each other, the beveled distal tip comprising a leading edge and a trailing edge, all of the longitudinal creases positioned generally opposite the side of the distal region on which the leading edge is positioned such that no longitudinal creases are positioned on the same side of the distal region on which the leading edge is positioned,” and “inflating a balloon that is positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand said distal region of said elongate tubular structure from said first, smaller cross-sectional profile to said second, greater cross-sectional profile.” Accordingly, Applicants respectfully request that the rejection of Claim 72 be withdrawn and that this claim be passed to allowance.

5. Independent Claim 87

Claim 87 recites and, for at least similar reasons as expressed above in relation to Claim 25, Nishtala, either alone or in combination with Fuqua and Durgin, fails to disclose, *inter alia*, “a circumferentially continuous elongate tubular structure,” “a tapered region between the distal region and the proximal region,” “the longitudinal creases of the distal region comprising two creased outer sections that lie on a perimeter of the distal region and face each other and two creased inner sections that lie within the perimeter of the distal region and face away from each other, all of the longitudinal creases generally positioned on one side of the distal region,” and “inflating a balloon positioned within an interior lumen of said folded distal region of said elongate tubular structure to expand and unfold said distal region of said elongate tubular structure from said first, folded, substantially continuous, smaller cross-sectional profile to said

second, unfolded, greater cross-sectional profile.” Accordingly, Applicants respectfully request that the rejection of Claim 87 be withdrawn and that this claim be passed to allowance.

6. Dependent Claims 27, 28, 49, 50, 62, 63, 74, 75, 83-86, 88 and 89

Claims 27, 28, 49, 50, 62, 63, 74, 75, 83-86, 88 and 89 each depend directly from one of independent Claims 25, 47, 60, 72 and 87. They are each believed to be patentably distinguished, *inter alia*, for the reasons set forth above in relation to the independent claim from which each depends and for the additional features recited therein. Accordingly, Applicants respectfully request that the rejections of Claims 27, 28, 49, 50, 62, 63, 74, 75, 83-86, 88 and 89 be withdrawn and that these claims be passed to allowance.

B. No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By: / Rabinder N. Narula/
Rabinder N. Narula
Registration No. 53,371
Attorney of Record
Customer No. 20995
(949) 760-0404